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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,384

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08/11/2010

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EXAMINER

COUGHLIN, MATTHEW P

ART UNIT

PAPER NUMBER

1626

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,384	Applicant(s) FAROUC ET AL.	
	Examiner Matthew P. Coughlin	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 21, 22 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 13, 14, 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 3, 4, 12, 15 and 29 is/are rejected.
- 7) ☒ Claim(s) 5-8 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-16, 21-22 and 29 are pending in the application. Claims 1, 2, 3, 4, 12, 15 and 29 are rejected. Claims 5-8 and 16 are objected to. Claims 9-11, 13-14 and 21-22 are withdrawn from further consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16th, 2010 has been entered.

Election/Restrictions

Applicant has elected, with traverse, the species of Example 93 to prosecute the invention of Group I, claims 1-22 and 29. This requirement is still deemed proper and was made final in the office action dated September 4th, 2009.

The claims within elected Group I have been examined to the extent that they are readable on the elected species of Compound 93. Since no prior art was found on the elected species, the examination was expanded within elected Group I until art was found, in which case, the examination stopped and art has been applied against the claims. Note, M.P.E.P. § 803.02.

The subject matter of the expanded search is as follows:

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The elected species, and

Compounds of formula I where W is oxygen and all other variables are as defined in claim 1.

As per MPEP 803.02, the examiner will determine whether the entire scope of the claims is patentable. According to MPEP 803.02:

Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable **, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As the Markush-type claim has been found not allowable, the Markush-type claims have been rejected and claims to the nonelected invention held withdrawn from further consideration. Claims 1-16, 21-22 and 29 have been examined to the extent that they are readable on the elected embodiment, the elected species of the compound of example 93. In previous office actions, the examiner had not withdrawn certain claims that do not read on the elected species; however, according to MPEP 803.02, claims that do not read on the elected species should be held withdrawn. Accordingly, since only claims 1-8, 12, 15-16 and 29 read on the elected species, all other claims have been withdrawn.

Subject matter not embraced by the above identified expanded search and Claims 9-11, 13-14 and 21-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **with traverse** in the reply filed on August 4th, 2009.

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Response to Amendment

The objection to claim 6 under 37 CFR 1.75(c) as failing to further limit is withdrawn based on Applicant's amendments to cancel "amino" from the Markush group of claim 6. The objection to claim 18 is withdrawn since claim 18 has been cancelled.

The rejections of claims 15, 17 and 18 under 35 USC 112 2nd paragraph as indefinite are withdrawn based on Applicant's amendments to the instant claims.

All previously made art rejections under 35 USC 102(b) have been withdrawn based on Applicant's amendments to the instant claims to limit the scope of Q to an alkylene group whereas all art rejections were directed to alkenylene groups in the Q position.

Claim Objections

Claims 5-8 and 16 are objected to as being drawn in part to non-elected subject matter. Should Applicant render the following claim rejections moot by amendment, the search would be expanded to include the subject matter of these claims, which is presently withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

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subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the instant claim 15 has been amended to provide definitions for the variables R5-R8 while the variables R1, R2, R3, and R3' are as defined in claim 1.

This subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As can be seen on page 19 of the specification, the invention as found in the originally filed application only provides for the instant particular definitions of R5-R8 when R1, R2, R3, and R3' are also limited to particular values.

Claims which change the scope relative to the originally filed claims may lack written description, see *In re Ruschig*, 371 F.2d 990, 154 USPQ 118 (CCPA) 1967) which supports that the original disclosure of a large genus did not support a later filed claim to a previously unnamed single species. Furthermore, *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir.2000) notes that with respect to *In re Ruschig*, that "Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say "here is my invention". In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure."

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The only written description in Applicants' originally filed disclosure is for the genus of claim 15 wherein the definitions of R1, R2, R3, and R3' have the same definitions are provided by the genus on page 19 for the compounds of formula II.

Claim Rejections - 35 USC § 102

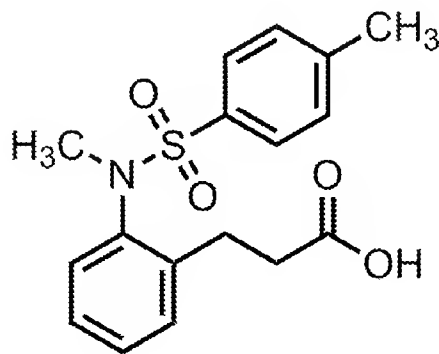
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 12, 15 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by German Patent document No. DE 3000519 A by Kraas et al. (English abstract attached in CAplus entry for DE 3000519)

Kraas et al. teach the following species as an aqueous solution in step a) on page 35 under example 5 (Beispiel 5):



The species depicted above is embraced by Applicant's variables in that:

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In claim 1, R1 is 4-methylphenyl; R2 is methyl; n is zero; Q is C2 alkyl; W is O; q is zero; and R3 is hydrogen. Furthermore, in claim 15, R5-R8 are hydrogen.

NOTE: Although not explicitly discussed herein, applicant is advised to note that this reference is replete with species representative of the instantly claimed genus and pharmaceutical compositions of the formula I. Consequently, any amendments to the claims to overcome rejections rendered under 35 U.S.C. § 102 should address this reference as a whole and should not be limited to the species discussed or disclosed explicitly herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

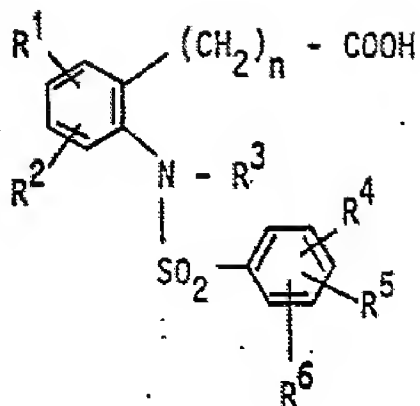
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over German Patent document No. DE 3000519 A by Kraas et al. (English abstract attached in CAplus entry for DE 3000519)

Determining the scope and contents of the prior art. (See MPEP § 2141.01)

Kraas et al. teach compounds of the following genus for use as hypoglycemics (see English abstract):

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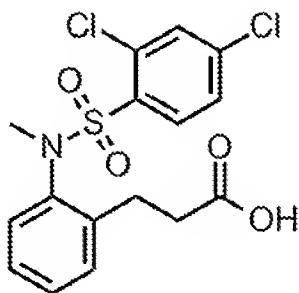


Ascertainment of the differences between the prior art and the claims. (See MPEP § 2141.02)

The difference between the prior art and certain compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

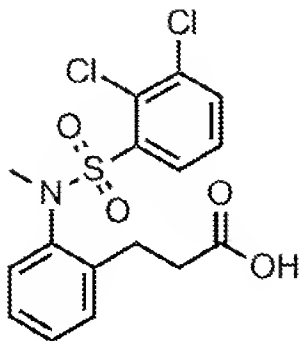
Finding of prima facie obviousness --- rationale and motivation (See MPEP § 2141.02)

Particular preference for compounds instantly claimed can be seen in the species cited in the 102(b) rejection above as well as the following compound which is taught on page 35 as example 6:



The species depicted above anticipates instant claim 1 and renders species within claim 3 obvious. For instance, Applicant's claims cover the following species:

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where the difference between the compound taught by the prior art and the instantly claimed species is that of positional isomerism. It is well established that position isomers are *prima facie* structurally obvious even in the absence of a teaching to modify. The isomer is expected to be preparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing the position isomers. This circumstance has arisen many times. See: *Ex parte Englehardt*, 208 USPQ 343, 349; *In re Mehta*, 146 USPQ 284, 287; *In re Surrey*, 138 USPQ 67; *Ex Parte Ulliot*, 103 USPQ 185; *In re Norris*, 84 USPQ 459; *Ex Parte Naito*, 168 USPQ 437, 439; *Ex parte Allais*, 152 USPQ 66; *In re Wilder*, 166 USPQ 545, 548; *Ex parte Henkel*, 130 USPQ 474; *Ex parte Biel*, 124 USPQ 109; *In re Petrzilka*, 165 USPQ 327; *In re Crownse*, 150 USPQ 554; *In re Fouche*, 169 USPQ 431; *Ex parte Ruddy*, 121 USPQ 427; *In re Wiechert*, 152 USPQ 247, *In re Shetty*, 195 USPQ 753; *In re Jones*, 74 USPQ 152, 154; and *In re Mayne*, 41 USPQ2d 1451 (in which the Court took notice of the extreme similarity between the amino acids leucine and isoleucine: "In fact, Leu is an isomer of Ile -- an identical chemical formula with differences only in the chemical bonding of the atoms. The side chains...of Leu and Ile have the same number of hydrogen and carbon atoms...The structure of Leu and Ile alone suggest their functional equivalency" (at 1454-1455)).

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For example, "Position isomerism has been used as a tool to obtain new and useful drugs" (Englehardt) and "Position isomerism is a fact of close structural similarity" (Mehta, emphasis in the original). Note also *In re Jones*, 21 USPQ2d 1942, which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to prima facie obviousness"; one of those listed is "adjacent homologues and structural isomers". Position isomers are the basic form of close "structural isomers." Similar is *In re Schechter and LaForge*, 98 USPQ 144, 150, which states "a novel useful chemical compound which is homologous or isomeric with compounds of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compounds." Note also *In re Deuel* 34 USPQ2d 1210, 1214 which states, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds ... a known compound may suggest its analogs or isomers, either geometric isomers (cis v. trans) or position isomers (e.g., ortho v. para)." See also MPEP 2144.09, second paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew P. Coughlin whose telephone number is (571)270-1311. The examiner can normally be reached on Monday through Thursday from 5:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew P. Coughlin/ Examiner, Art Unit 1626	/Rebecca L Anderson/ Primary Examiner, Art Unit 1626
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